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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/576,043	05/23/2000	Eric D. Blom	1069/66261	3542

23643 7590 07/02/2003

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INDIANAPOLIS, IN 46204

EXAMINER

MITCHELL, TEENA KAY

ART UNIT	PAPER NUMBER
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3761

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DATE MAILED: 07/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/576,043

Applicant(s)

BLOM, ERIC D.

Examiner

Teena K Mitchell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-22 is/are allowed.
- 6) ☒ Claim(s) 23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 May 2000 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2-5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION***Priority***

It is noted that this application appears to claim subject matter disclosed in prior Application No. 09/398,110, filed September 16, 1999. A reference to the prior application must be inserted as the first sentence of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. **Also, the current status of all nonprovisional parent applications referenced should be included.**

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C.

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119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A priority claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed claim for priority under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

While applicant does list the 09/360,110 application, applicant should also state the current status of the application and of all nonprovisional parent applications referenced should be included.

Information Disclosure Statement

In the IDS filed 6/25/0, paper number 5, it appears that two sheets should be present, however the examiner could only locate page 1 of 2, which is attached to this office action. If in fact there is suppose to be two sheets with this IDS, applicant is requested to submit page 2 in response to this action.

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Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the first, second, third, fourth, and fifth port (while these elements may be in a figure, they should be labeled to distinguish the locations of the five ports; inasmuch as the five ports are a critical part of the invention) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

The abstract of the disclosure is objected to because the Abstract is over 150 words in length (note CFR 1.72). Correction is required. See MPEP § 608.01(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 23, line 6, "...relatively more flexible material..." is indefinite; it is unclear as to what is meant by relatively more flexible material (i.e., more flexible than what? What constitutes a relatively more flexible material if the material is not more flexible

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than another element; is it to say that the cannula is formed from a material which is more flexible than the stylet?).

In claim 23, lines 6 and 7, "...relatively less flexible material..." is indefinite; it is unclear as to what is meant by relatively less flexible material (i.e., less flexible than what? What constitutes a relatively less flexible material if the material is not more flexible than another element; is it to say that the stylet is formed from a less flexible material than the cannula?).

Allowable Subject Matter

Claims 1-22 are allowable over the prior art of record.

Claim 23 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action.

The following is an examiner's statement of reasons for allowance: The overall combination of an outer cannula having a first port for orienting outside the neck of a wearer, a second port for orienting within the trachea of the wearer and a first passageway coupling the first port to the second port to permit the flow of gases from the first port to the second port during inhalation by the wearer and from the second port during exhalation by the wearer, a third port between the first and second ports, and an inner cannula for insertion into the first passageway via the first port when the wearer desires to be able to exhale through the wearer's pharynx, the inner cannula including a fourth port for orienting adjacent the first port, a fifth port for orienting adjacent the second port and a second passageway coupling the fourth port to the fifth port to permit

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the flow of gases from the fourth port to the fifth during inhalation by the wearer and from the fifth port during exhalation by the wearer, a valve controlling flow through the third port, the valve assuming a first orientation to permit flow from the first port to the second port when the first port is at a higher pressure than the second port, and a second orientation to permit flow from the second port through the third port when the second port is at a higher pressure than the first port; also the tracheotomy cannula wherein the cannula including a portion formed from a thermoplastic material having a first, generally curved orientation when said portion is maintained substantially below body temperature and a second, somewhat inverted L-shaped configuration when said portion is warmed substantially to body temperature is neither anticipated nor rendered obvious by the prior art of record .

Conclusion

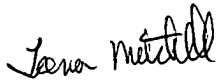
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of art is cited to show tracheotomy cannula devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teena K Mitchell whose telephone number is (703) 308-4016. The examiner can normally be reached on Monday-Friday during normal business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Weilun Lo can be reached on (703) 308-1957. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9302 for regular communications and (703) 872-9303 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



Teena Mitchell
Patent Examiner
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June 29, 2003